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PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference	FOR FURTHER ACTION	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
E SD/RS/VP41/8p		
International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/EP 99/ 04067	28/06/1999	26/06/1998
International Patent Classification (IPC) or national classification and IPC		
A61K38/40		
Applicant		
N.V. NUTRICIA et al.		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 7 sheets, including this cover sheet.

   ☐ This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

   These annexes consists of a total of 1 sheets.

3. This report contains indications relating to the following items:

   - I ☒ Basis of the report
   - II ☐ Priority
   - III ☒ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
   - IV ☐ Lack of unity of invention
   - V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
   - VI ☐ Certain documents cited
   - VII ☒ Certain defects in the international application
   - VIII ☒ Certain observations on the international application

CORRECTED VERSION

Date of submission of the demand	Date of completion of this report
26/01/2000	[illegible]
Name and mailing address of the IPEA/	Authorized officer
European Patent Office D-80298 Munich Tel. (+49-89) 2399-0, Tx: 523656 epmu d Fax: (+49-89) 2399-4465	Dominique Hundt

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/EP99/04067

I. Basis of the report

1. This report has been drawn on the basis of *(substitute sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to the report since they do not contain amendments (Rules 70.16 and 70.17).)*:
Description, pages:

1-41,42-52 as originally filed

Claims, No.:

2-22 as originally filed

1 with telefax of 29/09/2000

Drawings, sheets:

1/14-14/14 as originally filed

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language: , which is:

- ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in written form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

- ☐ the description, pages:

☐ the claims, Nos.:

☐ the drawings, sheets:

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)):

   (Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)

6. Additional observations, if necessary:

III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been examined in respect of:

   ☐ the entire international application.

   ☒ claims Nos. 19, 20, 22 in respect of IA.

because:

   ☒ the said international application, or the said claims Nos. 19, 20, 22, in respect of IA relate to the following subject matter which does not require an international preliminary examination (*specify*):
   see separate sheet

   ☐ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. are so unclear that no meaningful opinion could be formed (*specify*):

   ☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.

   ☐ no international search report has been established for the said claims Nos. .

2. A meaningful international preliminary examination report cannot be carried out due to the failure of the nucleotide and/or amino acid sequence listing to comply with the standard provided for in Annex C of the Administrative Instructions:

   ☐ the written form has not been furnished or does not comply with the standard.

   ☐ the computer readable form has not been furnished or does not comply with the standard.

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	1-10, 12-14, 17
	No:	Claims	11, 15, 16, 18-22
Inventive step (IS)	Yes:	Claims	1-10
	No:	Claims	11-22
Industrial applicability (IA)	Yes:	Claims	1-18, 21
	No:	Claims	

2. Citations and explanations
see separate sheet

VII. Certain defects in the international application

The following defects in the form or contents of the international application have been noted:
see separate sheet

VIII. Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:
see separate sheet

Comments on item III

1. Claims 19, 20 and 22 relate to subject-matter considered by this Authority to be covered by the provisions of Rule 67.1(iv) PCT. Consequently, no opinion will be formulated with respect to the industrial applicability of the subject-matter of these claims (Article 34(4)(a)(i) PCT).

Comments on item V

1. D1: WO 97 18827 A discloses antimicrobial agents comprising a polycationic peptide (lactoferrin) which may optionally contain a buffer. This document does not refer, however, to the pH of the tissue to be treated nor to the amount of buffer per unit dose of medicament.

1.1 The technical effect of this difference is a better control of the amount of the anti-microbial agent with an optimal pharmaceutical activity. The skilled in the art, when faced to the problem of finding an antimicrobial agent wherein the amount can be better adjusted than in the prior art, would not deduce a solution in view of D1 (or any of the other available documents). Hence, the subject-matter of claim 1 meets the criteria set forth in PCT with respect to novelty and inventive step.

1.2 Dependent claims 2-10 are allowable. See, however, item VIII with respect to some of the claims.

2. Having regard to the prior art, the subject-matter of claims 11, 15, 16 and 18-22 cannot be considered as novel (Article 33(2) PCT) for the following reasons:

2.1 The medicament of claim 11 is encompassed by the disclosure of D1. It should be noted that this claim attempts to define the subject-matter in terms of the result to be achieved, which merely amounts to a statement of the underlying problem (..."being present at a predeterminated level in order to yield a synergistic pharmaceutical effect ..." ; see also item VIII with respect to this claim). As the technical features necessary for achieving this result are not mentioned, the only

feature which could be used for comparing with the prior art is the fact that the medicament comprises a polycationic peptide or protein. This feature is disclosed by D1 (see page 5, lines 23-34 and p.26, l.9-10).
D1 discloses also the additional feature of claim 15 (see p.35, l.9-14).

2.2 The subject-matter of claims 16 and 18-22 is also anticipated by D1, which describes a composition containing a polycationic peptide (lactoferrin) and a buffer (see p.37), as well as its use for treating infections including candidiasis (see example 5).

2.3 The additional features contained in claims 12-14 and 17 are considered as being trivial for the skilled man, and in any case, the application does not contain any indications that these features involve a surprising effect. Hence, they cannot be regarded as involving an inventive step (Article 33(3) PCT).

3. For the assessment of the present claims 19, 20 and 22 on the question whether they are industrially applicable, no unified criteria exist in the PCT Contracting States. The patentability can also be dependent upon the formulation of the claims. The EPO, for example, does not recognize as industrially applicable the subject-matter of claims to the use of a compound in medical treatment, but may allow, however, claims to a known compound for first use in medical treatment and the use of such a compound for the manufacture of a medicament for a new medical treatment.

Comments on item VII

1. The word preventment, present in claim 1, should be substituted by prevention.

Comments on item VIII

1. The term "and the like", in claims 1, 19, 21 and 22, should be deleted, since it is vague and imprecise, thereby resulting in lack of clarity (Article 6 PCT). The same

applies to "consisting essentially of", in claims 3 and 5.

2. Claim 11 does not meet the requirements of Article 6 PCT in that the matter for which protection is sought is not clearly defined. The claim attempts to define the subject-matter in terms of the result to be achieved which merely amounts to a statement of the underlying problem. The technical features necessary for achieving this result should be added.

3. In claim 13 it is not clear if the medicament referred to comprises only a poly-cationic peptide plus an antifungal agent, or also the separately administrable medicament mentioned in claim 11; therefore claim 13 does not meet the requirements of Article 6 PCT.

4. Claim 17 is also unclear (Article 6 PCT), since it relates to the amount of peptide by referring to claim 10, which does not relate to the peptide, but to a "standard antifungal agent".

International pat.appln. PCT/EP99/04067
Enc. to letter dated: 29 September 2000

NEW CLAIM

1. Medicament for treatment and/or preventment of infections caused by bacteria, fungii, virii and the like, imflammations and/or tumors, said medicament comprising an active amount of a polycationic peptide or protein, and a buffer, characterised in that the buffer is present, per unit dose medicament, in an amount of at least 1 µmol, preferably 2 or more µmols for maintaining the pH of treatable tissue within a preselected range.